

SIMETHICONE- simethicone capsule, gelatin coated
Spirit Pharmaceuticals LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

ULTRA STRENGTH GAS RELIEF

Drug Facts

Active ingredient (in each softgel)

Simethicone 180 mg

Purpose

Antigas

Use

for the relief of

■ pressure and bloating commonly referred to as gas

Warnings

Keep out of reach of children.

Keep out of reach of children.

Directions

■ adults: swallow with water 1 or 2 softgels as needed after meals and at bedtime

■ do not exceed 2 softgels in 24 hours except under the advice and supervision of a physician

Other information

■ store at controlled room temperature 20-25°C (68-77°F)

■ protect from heat and moisture

Inactive ingredients

FD&C yellow #6, gelatin, glycerin, peppermint oil, povidone, purified water, sorbitol solution, titanium dioxide

Questions or comments?

1-888-333-9792

PRINCIPAL DISPLAY PANEL



SIMETHICONE

simethicone capsule, gelatin coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-4154
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)		DIMETHICONE	180 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
POVIDONE K30 (UNII: U725QWY32X)	
WATER (UNII: 059QF0KO0R)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange (OPAQUE)	Score	no score
Shape	OVAL	Size	15mm
Flavor		Imprint Code	161
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-4154-2	2 in 1 CARTON	04/29/2021	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	04/29/2021	

Labeler - Spirit Pharmaceuticals LLC (179621011)

Revised: 11/2021

Spirit Pharmaceuticals LLC